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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/766,366	01/28/2004	Pauline Pan	A0000367-03-EJF	2888

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Darryl C. Little, Esq.
Pfizer Inc.
201 Tabor Road
Morris Plains, NJ 07950

EXAMINER	
ROBERTS, LEZAH	
ART UNIT	PAPER NUMBER
1612	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/766,366	PAN ET AL.	
	Examiner	Art Unit	
	LEZAH W. ROBERTS	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 May 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-19 and 21-33* is/are pending in the application.

4a) Of the above claim(s) *28-30* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 3-19, 21-27 and 31-33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *15 Oct 2007 and 06 May 2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This Office Action is in response to the Amendment filed May 6, 2008. All previous rejections have been withdrawn unless stated below.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims

Claim Rejections - 35 USC § 112 – Scope of Enablement (New Rejection)

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3-19, 21-27 and 31-33 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for eliminating or suppressing plaque, gum disease and malodor, does not reasonably provide enablement for preventing plaque, gum disease or oral malodor. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Attention is directed to In re Wands, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing Ex parte Forman, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

1) the nature of the invention,
2) the breadth of the claims
3) the relative skill of those in the art,
4) the state of the prior art,
5) the predictability of the art,
6) the amount of direction or guidance provided,
7) the presence or absence of working examples, and
8) the quantity of experimentation necessary,

The instant specification fails to provide guidance that would allow the skilled artisan to practice the instant invention without resorting to undue experimentation, as discussed in the subsections set forth infra.

1) *The nature of the invention.* The invention discloses a composition comprising hinokitiol and at least one essential oil to prevent, inhibit or eliminate plaque, oral malodor or gum disease.

2) *The breadth of the claims.* The claims are broad because they read on "preventing".

3) *The relative skill of those in the art.* The relative skill of those in the art are PhD, MD, and MS.

4) *The State of the Prior Art.* The prior art discloses that hinokitiol is an antimicrobial agent, but makes no mention of its prophylactic ability to stop bacteria and microbes responsible for oral conditions from forming.

5) *The Predictability or Lack Thereof in the Art.* Prevention is not practical with plaque, gum disease and oral malodor. According to the American Dental Association, although tooth decay has declined, it can still be a problem for individual children and even teens and adults. This is because plaque, a sticky film of bacteria, constantly forms on your teeth. When you eat or drink foods containing sugars or starches, the bacteria in plaque produce acids that attack the tooth enamel. The stickiness of the plaque keeps these acids in contact with your teeth and after many attacks, the enamel can break down. In regards to mouth odor, according to the American Dental Association (http://www.ada.org/public/topics/bad_breath.asp), bad breath can be caused by food, dry mouth etc, other oral diseases can be caused by health problems (such as diabetes) or lack of getting the oral cavity professionally cleaned. Some agents used to treat diseases of the oral cavity, such as bad breath; only mask the odor, the food that caused the bad breadth must leave the system before bad breath can be stopped. Diseases such as periodontal disease begin with plaque that is not removed during daily cleaning. When plaque is not removed it turns into calculus. It is impossible to remove all calculus with daily brushing (http://www.perio.org/consumer/faq_general.htm, pages 1-4). The calculus, if untreated, causes gingivitis, the first stage of periodontal disease (Canadian Dental Association, pages 1-3). Therefore it is likely a small amount of gingivitis is present in between dental visits. In the case of the instant invention, the disclosed oral cavity diseases can be caused by different factors, therefore it is nearly impossible to protect against them all with one composition.

6) *The Amount of Direction or Guidance Present.* The disclosure teaches methods to make hinokitiol derivatives and to incorporate them into mouthwashes but lacks any type of guidance that would lead one to believe that prevention is possible. This guidance or lack thereof is not commensurate with the full scope of the claims.

7) *The Presence or Absence of Working Examples.* The examples in the specification are examples of compositions. There is a lack of examples using the compositions to treat patients with plaque, malodor or gum disease or examples where the compositions prevent plaque, malodor or gum disease from occurring.

8) *The Quantity of Experimentation Needed.* The applicant needs to provide examples of using the compositions on patients that show once the compositions are used plaque, oral malodor or gum disease no longer occurs.

Claim Rejections - 35 USC § 103 – Obviousness (Previous Rejection)

1) Claims 1, 6-7, 17, 21 and 27 were rejected under 35 U.S.C. 103(a) as being unpatentable over Miyahara et al. (US 4,693,888). The rejection is maintained.

Applicant's Arguments

Applicant argues, in contrast to Miyahara et al., the compositions of the present invention specifically require combining hinokitiol with an oral care effective amount of at least one essential oil in an oral carrier comprising about 20% to about 30% by weight

of ethanol for preventing, eliminating or suppressing plaque, gum disease and oral malodor. Nowhere does Miyahara teach such oral care benefits for hinokitiol apart from its claimed antigen-synergist combination, much less improving such benefits of hinokitiol by incorporating it with the specific elements of the present invention, as amended. Therefore, since Miyahara nowhere teaches or suggests the above-noted oral care benefits for hinokitiol in and of itself, much less teach combining hinokitiol with specific elements of the claimed invention for preventing, eliminating or suppressing plaque, gum disease and oral malodor, the compositions of the present invention, as amended, would not have been obvious over this reference. This argument is not persuasive.

Examiner's Response

Applicant is arguing intended use for the compositions, hinokitiol "for preventing, eliminating or suppressing plaque, gum disease and oral malodor", when in fact the claims are drawn to the compositions performing these functions and not hinokitiol by itself. Furthermore, the composition of the reference works by suppressing formation of dental plaque (col. 1, lines 5-8), which is the object of the compositions of the instant claims. Absent of unexpected results, it would be obvious to add hinokitiol to the oral compositions of the reference comprising a flavoring, which is an essential oil, because the reference suggests using hinokitiol in the disclosed compositions.

2) Claims 1, 3-19, 21-27 and 31-33 were rejected under 35 U.S.C. 103(a) as being unpatentable over Fand et al. (US 3,164,524) in view of Iyer et al. (US 5,939,050). The rejection is maintained.

Applicant's Arguments

Applicant argues, in contrast to the Iyer et al., the compositions of the present invention specifically require combining hinokitiol with an oral care effective amount of at least one essential oil in an oral carrier comprising about 20% to about 30% by weight of ethanol for preventing, eliminating or suppressing plaque, gum disease and oral malodor. Nowhere does Iyer teach such oral care benefits for hinokitiol apart from the cited antimicrobial agents, much less improving any such benefits of hinokitiol by incorporating it with the specifically claimed elements of the present invention. Furthermore, the Examiner contends that, "Iyer also discloses hinokitiol has antimicrobial effects, which is its oral care benefit." Applicants respectfully submit, however, that mere antimicrobial effectiveness does not necessarily translate into an "oral care benefit". A compound's antimicrobial activity versus planktonic organisms (i.e., freely floating organisms) does not establish that compound's effectiveness versus the "biofilm" organisms found in the oral cavity (i.e., adherent, organized microbial communities). As noted by Michael L. Barnett in his article (copy enclosed) entitled The Role of Therapeutic Antimicrobial Mouthrinses in Clinical Practice. Therefore, since Iyer nowhere teaches or suggests the above-noted oral care benefits for hinokitiol in and of itself, much less teach combining hinokitiol with specific elements of the claimed

invention for preventing, eliminating or suppressing plaque, gum disease and oral malodor, the compositions of the present invention, as amended, would not have been obvious over this reference. Iyer's inadequacy is not cured by combining it with either Fand or Tawlar. Fand nor Tawlar mention hinokitiol. Therefore, since neither Iyer, Fand nor Tawlar teach or suggest the above-noted oral care benefits for hinokitiol in and of itself, much less teach combining hinokitiol with specific elements of the claimed invention for preventing, eliminating or suppressing plaque, gum disease and oral malodor, the compositions of the present invention, as amended, would not have been obvious over these references in combination. This argument is not persuasive.

Examiner's Response

Fand and Talwar are the primary references in the corresponding rejections. Iyer is used to disclose components that are suitable for ethanol comprising compositions. Iyer also discloses hinokitiol has antimicrobial effects. Even if they are as Applicant discloses effective against "free floating organisms" and not biofilm organisms, they would still be effective against those free organisms that cause certain oral conditions. Therefore it would have been obvious to one of ordinary skill in the art to have incorporated the hinokitiol into the compositions of the primary references motivated by the desire to incorporate the hinokitiol for its antimicrobial effect. Furthermore the claims do not recite the oral care benefit of the hinokitiol but the oral care benefit of the composition. The compositions of Fand and Talwar are oral antiseptics and for improving oral hygiene, respectively, which would include such objectives as

"preventing" plaque, gum disease and oral malodor. Although hinokitiol is not mentioned in either the primary references, Iyer discloses combinations including hinokitiol inhibit bacteria that forms plaque (col. 2, lines 28-39). It would have been obvious to incorporate the hinokitiol in the compositions of the primary references to improve oral hygiene by inhibiting the bacteria that causes plaque.

3) Claims 1, 3-19, 21-27 and 31-33 were rejected under 35 U.S.C. 103(a) as being unpatentable over Talwar et al. (US 4,945,087) in view of Iyer et al. (US 5,939,050).

See Applicant's augments and Examiner's response above in subsection 2.

Claims 1, 3-19, 21-27 and 31-33 are rejected.

Claims 29 and 30 are withdrawn.

No claims allowed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LEZAH W. ROBERTS whose telephone number is (571)272-1071. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick F. Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lezah W Roberts/
Examiner, Art Unit 1612

/Frederick Krass/
Supervisory Patent Examiner, Art Unit 1612